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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,863	12/08/2000	Akihito Tsuchiya	001611	8842

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,863

Applicant(s)

TSUCHIYA, AKIHITO

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 20-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al.(US 4,971,698) in view of Yamada et al.(US 4,945,443) and Soon-Shiong et al.(US 5,700,848).

The reference of Weber et al. discloses a method and product for treating environmental pollutants which includes immobilization of a microorganism in a gel-type organic polymer which is contacted with the environmental pollutant (See column 3, line 32 to column 4, line 57, for a list of environmental pollutants).

The above claims differ by specifying that the microorganisms are incorporated with a polymer containing a sugar component in which fructofuranosyl groups(s) is/are bonded to a fructosyl group at the β -2,6 position or a polyamino acid.

The reference of Yamada et al. discloses that it is known in the art to immobilize microorganisms within xanthan gum which is a microorganism-produced polymer. The reference also discloses the use of a cationic metal salt (See column 4, lines 40-68).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize the microorganisms of the primary reference in a xanthan gum as suggested by Yamada et al. for the known and expected result of providing an

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alternative means recognized in the art to achieve the same result, immobilization of microorganisms for contact with a substrate to be acted on by the immobilized microorganisms.

While the reference of Yamada et al. is drawn to the microorganism-produced polymer, xanthan gum, the instant claims differ by reciting the use of polymers, levan (a polymer containing a sugar component in which fructofuranosyl groups(s) is/are bonded to a fructosyl group at the β -2,6 position) or polyamino acid polymer.

The reference of Soon-Shiong et al. discloses a list of known polymers in the art for the immobilization of microorganisms. The list discloses that levan and polyamino acids are equivalents to the xanthan gum of Yamada et al. and alginate, carrageenan and chitosan of Weber et al. (See column 6, lines 51 to column 7, line 6).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any of the known polymer materials for immobilization of microorganisms while maintaining conditions which maintain the efficiency of the treatment system.

With respect to the specifics of the microorganisms, the reference of Weber et al. discloses the use of *Pseudomonas* (See Example 5) and mixed cultures of microorganisms (See column 2, lines 1-27) for immobilization within the polymer.

With respect to the “at least 65%” limitation, when using only one polymer as the immobilization agent, as is suggested by the prior art, the amount of polymer would be 100% which meets the instant claim limitation.

Response to Arguments

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3. Applicant's arguments filed 17 March 2003 have been fully considered but they are not persuasive.

In response to the combination of the references of Weber et al. in view of Yamada et al. and Soon-Shiong et al., Applicant has filed a declaration under 37 CFR 1.132.

The declaration under 37 CFR 1.132 filed 17 March 2003 is insufficient to overcome the rejection of the claims based upon the combination of the references of Weber et al. in view of Yamada et al. and Soon-Shiong et al. as set forth in the last Office action because: The unexpected results displayed in the declaration are not commensurate in scope with the claimed invention.

The declaration filed under 37 CFR 1.132 includes three examples that provide unexpected results. The first example is a "polyamino acid-containing microbial treatment agent" which is disclosed as L-glutamic acid- γ -benzyl ester having a molecular weight of 220,000. The second example is a "*Bacillus* bacteria-produced mucin-containing microbial treatment agent". The third example is a "*Zoogloea* bacteria-producing polysaccharide-containing microbial treatment agent". The instant claims include the claim language as follows to describe the polymer employed as a polymer/microorganism treatment agent: I) a cohesive or adhesive polysaccharide produced from bacteria of the genus *Zoogloea*; II) a levan produced from bacteria of the genus *Bacillus*, *Acetobacter*, or *Pseudomonas*; III) a polymer containing sugar component in which fructofuranosyl group (s) is/are bonded to a fructosyl group at the β -2,6 position; and IV) a polyamino acid. Example one of the declaration is not commensurate with claim limitation IV above because the declaration only displays unobviousness with respect to a single species of a broader claimed genus. Note the single species exemplified in the

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declaration does not provide an adequate basis for concluding that similar results would be obtained for other polyamino acids or even other glutamic acids. Example two of the declaration is not commensurate with any of the claimed limitations. The instant claims and entire originally filed disclosure are silent as to the use of a mucin polymer. Example three of the declaration is commensurate with claim limitation I above, however, the claims are not limited to this single claim limitation. The claim which includes this claim language as includes alternative claim language II and III.

Applicant's amendments filed 17 March 2003 are sufficient to overcome the 35 USC 102 rejection of record.

With respect to the combination of the references of Weber et al. and Yamada et al., Applicant argues that the combination of the references does not result on the instantly claimed invention. Applicant stresses that the combination does not encompass the microorganism produced polymers of the instant claims.

In response, applicant's amendments filed 17 March 2003 no longer include the broad claim language "a microorganism-produced polymer". The instant claims now are limited to more specific polymers. As a result, the rejection of the claims over Weber et al. in view of Yamada et al. is no longer applicable against the instant claims.

With respect to the combination of the references of Weber et al., Yamada et al. and Soon-Shiong et al., Applicant argues that the combination is improper because the reference of Soon-Shiong et al. merely discloses a list of biocompatible polymers and does not teach polymers usable in a microbial treatment agent for an environmental pollutant.

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In response, the reference of Soon-Shiong et al. was relied upon by the examiner as a tertiary reference which establishes that levan and glutamic acid are art recognized equivalents to the microorganism immobilization polymers disclosed by the references of Weber et al. and Yamada et al. As a result, in the absence of a showing of unexpected results, the prior art of record suggests substituting one equivalent for another. As discussed above, the declaration filed under 37 CFR 1.132 is not commensurate in scope with the claimed invention in terms of showing unexpected results.

With respect to Applicant's comments concerning the difference between a polysaccharide and a polyamino acid, for the same reasons set forth in the paragraph above, the reference of Soon-Shiong et al. establishes an art recognized equivalence between a polysaccharide and a polyamino acid in terms of immobilizing microorganisms in a polymer material.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

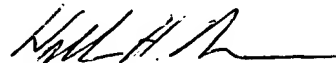
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB
May 30, 2003